Status **Active** PolicyStat ID **15951565**

Origination	7/14/2020	Document Contact	Michele Sedlak: Lab Quality Coord
Last Approved	7/17/2024	Area	Laboratory-Quality
Effective	7/17/2024	Applicability	All Beaumont Hospitals
Last Revised	7/17/2024	Key Words	GEN.20340
Next Review	7/17/2026		

Laboratory Procedure for the Management of Vendor Notifications of Defects/Issues

COPY

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This procedure is to define the process by which the laboratory is alerted to product recalls/issues, and to define the process to follow in effectively responding to these notifications.
NOTE: For any blood or blood component recalls, market withdrawals, or lookbacks, please refer to the blood bank procedure specific for the blood bank hospital location. It is most important that the laboratory is made aware of product recalls, market withdrawals and software issues which may have the potential to affect laboratory testing/results. It is also important that the laboratory has a defined, effective process for taking action in response to these important notifications.

II. DEFINITIONS:

A. **ManageRecalls** is a comprehensive, web-based service that automates alert-management for subscribing organizations.
Corewell Health East (to include the laboratory) uses the ManageRecalls system to receive and respond to product-related alerts/recalls.

III. PROCEDURE:

A. ManageRecalls monitors multiple sources of alerts and recalls and combines them into a single alert repository.

B. ManageRecalls reviews each alert and applies filters to identify and send only the alerts

relevant to the organization.

C. Once the ManageRecalls alert is ready, the filters will send the alert based on purchase history and subscribed product types.

D. An e-mail message (sent from ManageRecalls) is received directly into the Outlook mailbox of the Laboratory Alert Coordinator/Responder. This e-mail alerts of the new assignment/product alert.

E. The Lab Alert Coordinator/Responder clicks on the ManageRecalls link provided in the e-mail (https://manage.managerecalls.com/mrc/login.action) and then signs in to the ManageRecalls system using their User ID (email address) and Password.

F. The Lab Alert Coordinator/Responder clicks on the **Workspace** link at the top of the page. Under **My Alerts** is a list of open alerts. Locate the alert in the list. Click on the Alert title to view the full alert details. Send the information to the respective lab area for review and follow up.

G. When the manager/supervisor responsible for the alert-follow-up responds back to the Lab Alert Coordinator/Responder, (i.e. Is product in stock/on-hand, is the product not used at the site, was the product used and supply exhausted), the Lab Alert Coordinator/Responder enters this information into the ManageRecalls system by clicking on the **Add Response** button when viewing the alert details. Complete all relevant fields on the **Add Response** form and select the appropriate task status based on the information entered in the task (On Hold, In Progress or Complete).

H. Send ALL alerts and/or recall notices received at your facility via:

   1. email: notices@managerecalls.com
   2. Fax: 925-226-3171

I. The Lab Alert Coordinator/Responder retains a copy of the completed Alert Detail Report for a minimum of 11 years. This documentation is needed for the College of American Pathologists (CAP) inspection.

COPY

IV. SPECIAL NOTES:

A. The College of American Pathologists (CAP) requires that “The laboratory manages notifications from vendors of defects or issues with reagents, supplies, instruments, equipment, or software that may affect patient care/client services." Evidence of Compliance with this requirement are:

   1. Records of manufacturer’s recalls received AND
   2. Follow-up documentation

B. Records of manufacturer’s recalls and follow-up documentation are filed by the Lab Alert Coordinator and/or Responder.

C. Each site has a Laboratory Alert Coordinator and Laboratory Alert Responder assigned.

V. ATTACHMENT:

ManageRecalls Quick Reference Guide, 2024

VI. REFERENCES:

A. Laboratory General Checklist, College of American Pathologists (CAP), current version.
B. Manage Recalls Training and Development Guide, Course: Management Role 2015
C. Product Recall and Alert
D. Record Management, Retention and Destruction Policy
E. Record Storage and Destruction Procedure

Attachments

ManageRecalls Quick Reference Guide 2022

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	7/17/2024
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	7/17/2024
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	7/17/2024
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	7/17/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	7/16/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	7/16/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	7/16/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	7/16/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	7/16/2024

COPY

Policy and Forms Steering Committee Approval (if needed)	Michele Sedlak: Lab Quality Coord	7/16/2024
	Sarah Britton: VP, Laboratory Svcs	7/16/2024
Operations Directors	Joan Wehby: Dir, Lab Services	7/16/2024
Operations Directors	Elzbieta Wystepek: Dir, Lab Operations B	6/4/2024
Operations Directors	Brittnie Berger: Dir Sr, Lab Operations	6/4/2024
Operations Directors	Amy Knaus: Dir, Lab Operations C	6/3/2024
Operations Directors	Christopher Ferguson: Dir, Lab Operations B	6/3/2024
	Michele Sedlak: Lab Quality Coord	6/3/2024

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne

COPY